The Medical Algorithmic Audit: a protocol for safety monitoring of a skin cancer detection artificial intelligence health technology

Dr Aditya U Kale MBChB,[1] Dr Xiaoxuan Liu PhD,[1] Prof Alastair K Denniston PhD[1]

[1] College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK [2] Ophthalmology Department, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

Background

Artificial Intelligence (AI) has the potential to transform healthcare. Novel AI health technologies are being developed for a wide variety of clinical tasks with diagnostic, prognostic and therapeutic applications. Although there has recently been a high degree of interest and hype in this field, AI health technologies are still not widely utilized in routine clinical practice. One of the most important reasons for this "AI chasm" is the lack of consensus around how best to ensure the safety of these devices once they have been deployed in a clinical setting. As with any medical device, AI as a medical device has the potential to fail. AI errors have an impact on the overall clinical process, ultimately having the potential for patient harm. *The Medical Algorithmic Audit,* proposed by Liu et al (*Lancet Digital Health* 2022) is a safety monitoring framework that aims to better understand the weaknesses of algorithms and put in place risk mitigation strategies. This clinical abstract aims to demonstrate the application of the medical algorithmic audit to DERM AI (Skin Analytics) which is a CE marked AI health technology deployed in University Hospitals Birmingham NHS Trust.

Methods

This study aims to employ mixed methods analysis to evaluate *The Medical Algorithmic Audit* in the context of the Skin Analytics DERM AI, which has been deployed as a streaming and triage tool for patients with suspected skin cancer. The audit process intends to be interdisciplinary and collaborative between users (clinical teams) and developers. The SMACTR audit process applied to DERM AI will consist of:

- Scoping: Intended use and impact
- Mapping: Personnel and resources for audit, AI system and the healthcare task
- Artifact collection: Gathering of documents and materials which may inform the audit
- Testing: Exploratory error analysis, subgroup testing and adversarial testing
- Reflection: Recommendation of developer and user actions based on the audit outcome

An important component of the study will be interviews with audit stakeholders to gain qualitative insights into the audit process including how the framework is translated and implemented in a clinical setting, its effectiveness in supporting the detection and reporting of safety issues, and its integration or alignment with pre-existing governance and audit activities.

Discussion

There is a clear need for a collaborative effort in real world safety monitoring of AI health technologies, including stakeholders such as clinical teams, AI developers and regulatory bodies. *The Medical Algorithmic Audit* framework has the potential to engage multidisciplinary stakeholders in safety assessment and monitoring of AI health technologies post-deployment. This particular algorithmic audit will form the first of several audits with associated qualitative study, aiming to modify and operationalise this tool. This clinical abstract aims to 1) demonstrate the application of the audit process to an example AI health technology in a protocol format, and 2) provoke discussion amongst clinical and computational researchers around how AI errors can be pre-empted, detected, and analyzed to prevent downstream patient harm.